REMARKS

Claims 6-19, 26, 31-35, and 37 are pending in this application. Claims 26 and 37 have been amended. No new matter has been added. Applicant believes these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicant respectfully submits that the claim amendments do not limit the range of any permissible equivalents.

35 U.S.C. §112 Rejection (Written Description)

Claims 3-19, 26, 31-35, and 37 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner seems to be making two arguments in this regard. First, it is asserted that the specification fails to describe the details of how the agents "are incorporated in the membrane of the filter bag." Second, it is asserted that the "specification does not provide as to amounts of medicinal agents incorporated into the filter bag." For the reasons set forth below, Applicant respectfully disagrees and submits that the subject matter of claims 6-19, 26, 31-35, and 37 is fully supported by the specification.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.

In this case and as previously set forth in a prior Response, all of the claim elements that appear to be the basis for the written description rejection were present in the original claims. Thus, there is a strong presumption that an adequate written description of the invention as embodied in this element is present in the specification as filed. The presumption is even more applicable in this case as there were three Office Actions issued prior to the written description

and enablement rejections being first raised.

More importantly and contrary to the Examiner's assertions, Applicant has described how the medicinal agents "are incorporated in the membrane of the filter bag" and the "amounts of medicinal agents incorporated into the filter bag." With respect to the latter, the claims, as originally filed and as currently pending recite "a therapeutic effective amount of at least one medicinal agent." This phrase is used throughout the specification and is defined in the specification as "an amount that produces the desired therapeutic response upon oral administration, and can be readily determined by one of ordinary skill in the art. In determining such amounts, the particular medicament being administered, the bioavailability characteristics of the medicament, the dose regime, the age and weight of the intended recipient, and other factors should be considered." Applicant respectfully submits that it is not necessary to satisfy the written description requirement to provide an absolute amount of a given medicinal agent. In this case, such information is known or readily available to those of ordinary skill in the art.

With respect to the former, the specification does provide methods for incorporating the medicinal agent into the porous material. As illustrated in FIG. 2, the medicament 10 is sandwiched in between a lower filter bag material layer 30 and an upper filter bag material layer 40. (Page 7, lns. 10-11). In one embodiment, a drug releasing element, such as gelatin, may be impregnated on the surface of the filter bag material after applying the medicament, thus sandwiching the medicament between the gelatin layer and the filter bag material. (Page 7, lns. 24-26).

In light of the foregoing, reconsideration and withdrawal of the written description requirement rejection is respectfully requested.

35 U.S.C. §112 Rejection (Enablement)

Claims 3-19, 26, 31-35 and 37 were also rejected under 35 U.S.C. 112, first paragraph as not being enabled. For the reasons set forth below, Applicant respectfully disagrees and submits that claims 6-19, 26, 31-35, and 37 are enabled by the specification.

As an initial matter, Applicant notes that the Examiner is still maintaining that the specification is enabling for a filter bag coated with aspirin or sildenafil citrate. While this

acknowledgement is appreciated, it ignores Applicant's arguments set forth in the prior Response with respect to other specific agents. In particular, the specification discloses a number of other specific agents for coating a filter bag, namely; antihistamine drugs such as H_2 blockers; vitamins and minerals such as traces of selenium, chromium, molybdenum, zinc, and copper, electrolytes, gold compounds; oligosaccharides such as fructo-oligosaccharides, pyruvate precursors in the form of pyruvamide, or pyruvyl-amino acids, such as, pyruvyl-glycine, pyruvyl-alanine, pyruvyl-leucine, pyruvyl-valine, pyruvyl-sarcosamine and their amides. (Page 6, lns.14-24). In short, Applicant respectfully submits there is no basis for finding the specification enabling only for two of the numerous specific examples of medicinal agents provided in the specification.

Two arguments are made in support of the enablement rejections. Each of which is now addressed. First, it is asserted that the "specification provides no guidance as to how to prepare the medicament such that it is incorporated in the bag material i.e., as a powder or solubilized and applied [as] liquid coating etc." In addition, it is asserted that the "specification fails to provide details of the conditions (such as temperature) of coating or incorporating the desired agents without loosing [sic] the activity of the compounds." Applicant notes once again that the preparation of medicinal agents in powder or liquid forms is well known to one skilled in the art and that such information could be obtained without undue experimentation. One of ordinary skill would also appreciate that the temperature should be controlled to avoid inactivation of the medicinal agent. As such, the specification is not required to teach methods for preparing the medicinal agents and it is preferable that the specification omits such teachings. As also previously noted, the specification does provide methods for applying the medicinal agent to the porous material.

Second, it is asserted that the Applicant has "not described if all of the materials claimed i.e., drugs or nutrients or other beneficial agents, are soluble upon contact with liquid, or any mechanism as to how the medicaments claimed are released." The specification provides teaching as to release of the medicinal agent. Specifically, the medicament solubilizes when in contact with liquid and is dispersed in the proper dosage amount into the liquid for oral consumption. (Page 5, lns. 29-31). Additionally, upon immersion in a liquid 70, the gelatin layer 40 breaks down into gelatin particles 40a, which dissolve into the liquid 70, and the

medicament 10 is released into the liquid 70, as depicted in FIG. 4. (Page 7, lns. 29-32). Applicant respectfully submits that it is not necessary to set forth the solubility limits of every medicinal agent in a particular liquid at a given temperature range. Rather, the solubility of these medicinal agents is well known to one skilled in the art such that such information could be obtained without undue experimentation. More importantly, the claims are limited by the specification which requires that the medicament "must be dispersible in the medium of the liquid for ingesting during an interval just prior to or during feeding, in order to meet the objectives of the invention."

In light of the foregoing, Applicant submits that claims 6-19, 26, 31-35 and 37 are enabled by the specification. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 112 rejection.

Claim Amendments

As set forth above, it is Applicant's position that the claims satisfy all requirements for patentability. Nevertheless and in an effort to expedite prosecution without the need for a Board decision, independent claims 26 and 37 have been amended. Claim 26 now recites that the medicinal agent is either aspirin or sildenafil citrate. Claim 37 now recites that the medicinal agent is aspirin, sildenafil citrate, or one of the agents that affects the cardiovascular system previously recited in claim 3 (which agents are well-known). Applicant notes that by making these amendments (including the cancellation of dependent claims), the claims no longer recite any of the medicinal agents the Examiner cited as broad genus of species.

Conclusion

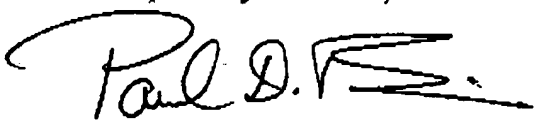
For all of the above reasons, the claim rejections are believed to have been overcome, placing claims 6-19, 26, 31-35, and 37 in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

No fee is believed to be due. However, please charge any required fee (or credit any

overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 795-A03-012).

Respectfully submitted,



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